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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/934,323 | 08/21/2001 | Rory A.J. Curtis | MPI00-336P1RM | 8135 |
| 7590 | 03/08/2004 | | EXAMINER NASHED, NASHAAT T | |
| INTELLECTUAL PROPERTY GROUP MILLENNIUM PHARMACEUTICALS, INC. 40 LANDSDOWNE STREET CAMBRIDGE, MA 02139 | | | ART UNIT 1652 | PAPER NUMBER |

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,323

Applicant(s)

CURTIS, RORY A.J.

Examiner

Nashaat T. Nashed, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/16/02 & 10/11/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election without traverse of Group I, claims 1-4, and 8, in the communication filed January 21, 2004 is acknowledged.

The application has been amended as requested in the communication filed January 21, 2004. Accordingly, claims 1-20 have been canceled, and claims 21-32 have been entered and under consideration.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For examples, see pages 12, 14, 15, 27, and 28.

The disclosure is objected to because of the following informalities: it contains a reference to accession number without the number.

Appropriate correction is required.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicant discloses the nucleic acid sequence of SEQ ID NO: 1 comprising the open reading frame of SEQ ID NO: 3 encoding the human amino acid sequence of SEQ ID NO: 2. Based on reasonable sequence homology (97.9%) to a rat protein named neuroligin 2, the protein of SEQ ID NO: 2 is thought to be a human neuroligin. Also, applicants thought the protein has a carboxylesterase activity based on the fact that neuroligin has a carboxylesterase domain. The carboxyl esterase domain in SEQ ID NO: 2 corresponds to residues 42-601 which is nearly identical to residues 42-601 of neuroligin 2 reported by Lichtchenko *et al.* (two serine residues and one threonine residue of Lichtchenko *et al.*'s protein are substituted with two prolines and alanine in SEQ ID NO: 2, see IDS filed 1/16/02, reference AK). The teaching of Lichtchenko *et al.*, however, indicates that the esterase domain of three different neuroligins including neuroligin 2 are dormant and do not have esterase activity because the active site serine residues are replaced with a conserved glycine residues among neuroligins, see Lichtchenko *et al.*, page 2679, right column, first paragraph. Thus, it is clear that the protein of SEQ ID NO: 2 does not have an esterase activity of any kind. While neuroligins, in particular neuroligin 2 appear to be an important class of proteins, the prior art does not teach their specific biological function or their relationship to any known disease or syndrome. Also, the specification has not identified any specific

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credible chemical or biological function or use. The specification describes non-specific functions for the protein, nucleic acid, and antibodies, see for example pages 39-40 and 57-87. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 2 which neither the gene or the polypeptide associated with any specific use or a disease. The mere fact that the polypeptide disclosed in the specification is named 33410 novel human carboxylesterase is indicative that the applicants have no idea about the specific function of this protein at the time they filed their application. It appears that the main utility of the polypeptide and nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with utility requirement of 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the nucleic acid sequence encoding the protein of SEQ ID NO: 2

Claims 21, 23, 25, 27, 28, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 is directed to all possible DNAs which are 95% homologues to SEQ ID NO's: 1 and 3 or encodes a protein that is 95% homologues to SEQ ID NO: 2. The specification, however, only provides a single representative species from human encompassed by these claims, which applicants assert encodes a carboxylesterase activity. Evidence in the prior art, however, indicates that the protein of SEQ ID NO: 2

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has no carboxylesterase activity. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Claims 23, 25, 27, 28, and 31 are included in this rejection because they are dependent on a rejected claim and do not cure its deficiencies.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 23, 25, 27, 28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ichtechenko *et al.* (IDS: J. Biol. Chem. 1996, 271, 2676-2686).

Ichtechenko *et al.* teach the nucleic and the amino acid sequence of neuroligin 2 from rat brain, see abstract and Figures 2 and 3. The 836 amino acid residue neuroligin 2 from rat is 98.3% identical to SEQ ID NO: 2, and the nucleic acid from rat is >90% identical to SEQ ID NO: 3 (claim 21). Also, Ichtechenko *et al.* teach vector and host cell comprising the nucleic acid and a recombinant method of making neuroligin 2 (claims 23, 25, 27, 28, and 31), see the Experimental Procedures starting on page 2676 through the end on page 2677.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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